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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/562,021 | 01/11/2006 | Allan Svendsen | 10340.204-US | 7949 |

25908 7590 06/17/2009

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| EXAMINER | |
|---|---|
| HA, JULIE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/17/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/562,021 | SVENDSEN ET AL. | |
| | Examiner | Art Unit | |
| | JULIE HA | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Sequence listing filed on September 30, 2008 is acknowledged. Claims 1-14 are pending in this application.

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, drawn to a method of producing a variant polypeptide, which method comprises (a) providing an amino acid sequence, (b) superimposing the two three-dimensional models, (c) selecting an amino acid residue in the CGTase, (d) modifying the CGTase sequence, wherein the modification comprises substitution or deletion of the selected residue or by insertion of a residue adjacent to the selected residue, and (e) producing the polypeptide having the resulting amino acid sequence.

Group 2, claim(s) 6, 8-12, drawn to a polypeptide which (a) has an amino acid sequence having at least 70% identity to SEQ ID NO: 6, (b) compared to SEQ ID NO: 6, comprises at least one additional amino acid in a region corresponding to amino acids 194-198, (c) compared to SEQ ID NO: 6 has a different amino acid or an insertion or deletion at a position corresponding to amino acid 16, 47, 85-95, 117, 139, 145, 146, 152, 153, 168, 169, 174, 184, 191, 260-269, 285, 288, 298, 314, 335, 413, 556, 602 or 677, and (d) has the ability to form linear oligosaccharides as an initial product when acting on starch.

Group 3, claim(s) 7, drawn to a polypeptide which (e) has an amino acid sequence having at least 70% identity to SEQ ID NO: 6, (f) compared to SEQ ID NO: 6, comprises at least one additional amino acid in a region corresponding to amino acids 260-269, (g) compared to SEQ ID NO: 6 has a different amino acid or an insertion or deletion at a position corresponding to amino acid 16, 47, 85-95, 117, 139, 145, 146, 152, 153, 168, 169, 174, 184, 191, 260-269, 285, 288, 298, 314, 335, 413, 556, 602 or 677, and (h) has the ability to form linear oligosaccharides as an initial product when acting on starch.

Group 4, claim(s) 13, drawn to a polynucleotide encoding the polypeptide of claim 6.

Group 5, claim(s) 14, drawn to a method for preparing a baked product which comprises adding the polypeptide of claim 6 and baking the dough to prepare the baked product.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the polypeptide of claim 6 is taught by WO 99/43793 A (filed with IDS). WO 99/43793 A teaches a polypeptide having at least 70% identity with parent CGTase (Thermoanaerobacter CGTase, see bottom of page 3). This polypeptide has at least one mutation at the regions selected in a group comprising the regions corresponding to amino acids 78-85, 136-139, 173-180, 188-195, and 259-268. The positions 78-85 and 136-139, 173-180, 188-195, and 259-268 overlap the positions 85-95, 139, 174, 191 and 260-269 of instant claim 6. Furthermore, the reference teaches that said modification can include the insertion of DPAGF at positions corresponding to D190-F194 (see p. 4, line25, and Figure 4), corresponding to the position between residues 196 and 197 of instant SEQ ID NO: 6. The modifications can comprise further modifications between residues 87-94, 194-196 (including substitutions L to F and D to S at positions corresponding to residues 195 and 197) or 260-268 (including insertion of AN between V266 and D267 (see p. 4, lines 34-35). Therefore, the special technical feature of Group 2 was known in the art. Therefore, there is lack of unity of invention.

***Election of Species***

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different selection of amino acid residue in the CGTase: from claim 1(c);

Different charge of the amino acid: positive, negative, hydrophilic or hydrophobic;

Different non-selected amino acid: different due to amino acid functional groups;

Different variant polypeptide: different due to different amino acid residues;

Different polypeptide having at least 70% identity to SEQ ID NO: 6;

Different amino acid or insertion or deletion at different positions: from claim 6(c) or 7 (g);

Different one additional amino acid in a region corresponding to amino acids 194-198 of claim 6(b): from claim 8 or 9, for example;

Different one additional amino acid in a region corresponding to amino acids 260-269 of claim 7(f);

Different amino acid residue present at the corresponding position of SEQ ID NO: 17 or deletion of an amino acid residue in SEQ ID NO: 16;

Different polypeptide sequences: TLAGTDN, YGDDPGTANHL or YGDDPGTANHLE;

Different substitutions: from claim 12.

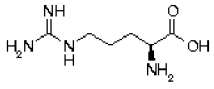
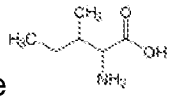
5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner:

Claims 2, 4, 9, 11, and 12.

The following claim(s) are generic: Claims 1, 3, 5-8, 10, 13-14.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different amino acid residues are patentably independent and distinct due to their different functional groups, leading to different structure. Different charges of the amino acid residues are patentably independent and distinct due to their different charges and structures. Further, search for one would not necessarily lead to the other. For example, Arginine is a positively charged amino acid having the structure  ; isoleucine is a hydrophobic amino acid having the structure  . Further, search for one would not necessarily lead to the other. Therefore, different non-selected amino acid residue in the CGTase sequence would be patentably independent and distinct due to their different structures. Different variant polypeptides are patentably independent and distinct due to their different amino acid content, leading to different structures. For example, a polypeptide having at least 70% identity to SEQ ID NO: 6 (which has 683 residues) would require at least 479 amino acids homology. This implies that 204 amino acid residues may be different. Additionally, there are different amino acid substitutions, insertions, or deletions, leading to different amino acid content, leading to different structures. For example, a polypeptide having at least 70% sequence identity to SEQ ID NO: 6, and having substitution of G181D and TLAGTDN at positions corresponding to 85-95 is patentably independent and distinct from a polypeptide having at least 70% sequence identity to SEQ ID NO: 6, and having an insertion of DPAGF at position 14-198. Further, search for one would not necessarily lead to the other. Therefore, different amino acid insertion, deletion at different positions, insertion of one additional amino acid insertion at region corresponding to amino acids 194-198 or 260-269, different amino acid insertion of TLAGTDN, YGDDPGTANHL or YGDDPGTANHLE at different positions, and amino acid substitutions are patentably independent and distinct because these lead to different polypeptide structures. Further, search for one would not necessarily lead to the other.

9. If an election is made from Group 1, Applicant is required to elect a single

disclosed species of amino acid residue, type of charge of the amino acid residue, and

a variant polypeptide. If additional group, such as additional non-selected amino acids are involved in the methods, Applicant is further required to elect a single disclosed species of a non-selected amino acid from claim 3. Please note, if an election to a non-selected amino acid is not elected, this will not lead to an examination of non-selected amino acid of CGTase from claims 3 and 4. If Group 2 is elected, Applicant is required to elect a single disclosed species of a polypeptide, including all of the variables (i.e., additional amino acid in a region corresponding to amino acids 194-198) and if the polypeptide Has an insertion or deletion at a position, indicating the positions, and electing a species of insertion or deletion at that position. For example, Applicant elects additional amino acid of DPAGF corresponding to amino acids 194-198, and substitution V16A of SEQ ID NO: 6. If Group 3 is elected, Applicant is required to elect a single disclosed species of polypeptide, including all of the variables (i.e., additional amino acid in a region corresponding to amino acid 260-269) and a substitution at G556S of SEQ ID NO: 6. If Group 4 is elected, Applicant is required to elect a single disclosed species of polypeptide including all of the variables that would arrive at a single disclosed species of polynucleotide that encode the polypeptide sequence. If Group 5 is elected, Applicant is required to elect a single disclosed species of polypeptide including all of the variables that would arrive at a single disclosed species of polypeptide, for example, SEQ ID NO: 6 comprising a T17R substitution.

10. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement

may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

11. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

12. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

13. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

14. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

16. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654